Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Complete if Known Substitute for form 1449A/PTO 10/785,374 **Application Number** 2/24/2004 Filing Date INFORMATION DISCLOSURE First Named Inventor Summar et al. STATEMENT BY APPLICANT Art Unit 1638 (Use as many sheets as necessary) Diana B. Johannsen **Examiner Name** 1242/58 CIP Sheet 7 Attorney Docket Number

	U.S. PATENT DOCUMENTS									
Examiner	Cite Document Number		Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear					
Initials*	No.1	Number - Kind Code ^{2 (if known)}	MM-DD-YYYY	Applicant of Cited Document	Figures Appear					

			.,,							
		ermonanannannannannastanastanastaniaitettaniaitetaniititaatatainastatatatatatatatatatatatatatatatatatat	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,							

		43Hrrind=4243-31HHHHHHHHHHHHHHHHHHHHHHHHHHHHHHHHHHH								
		««««««««««««««««««««««««««««««««««««««		, , , , , , , , , , , , , , , , , , ,						
				, , , , , , , , , , , , , , , , , , ,						

		FOREIGI	N PATENT DOCU	MENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	1	EP 044119 A2	08-14-1991	Levere et al.		-
***************************************			***************************************			
						-

Examiner	Date	
Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

	ier the raperwent readelent tet	***************************************				
Substitu	ite for form 1449B/PTO			Complete if Known		
Gubolita				Application Number	10/785,374	
INF	ORMATION DISC	1 09	SURF	Filing Date	2/24/2004	
STATEMENT BY APPLICANT (Use as many sheets as necessary)				First Named Inventor	Summar et al.	
				Art Unit	1638	
				Examiner Name	Diana B. Johannsen	
Sheet	2	of	7	Attorney Docket Number	1242/58 CIP	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	2	Abman et al., "Role of endothelium-derived relaxing factor during transition of the	
***************************************		pulmonary circulation at birth," Am. J. Physiol., Vol. 259, pgs. H1921-H1927 (1990).	
	3	Abman, S. H.; Arch Dis Child Fetal Neonatal Ed (2002) 87: F15-F18.	
	4	Adelman et al., "In Vitro Deletional Mutagenesis for Bacterial Production of the 20,000- Dalton Form of Human Pituitary Growth Hormone," DNA, Vol. 2, pg. 183-193 (1983).	
	5	Advisory Action corresponding to U.S. Patent Application Serial No. 12/364,078 dated March 9, 2011.	
***************************************	6	Allen, J. and ATS subcommittee AoP, Am J Respir Crit Care Med (2003) 168: 356-396.	
	7	Artymiuk et al., "Biotin carboxylase comes into the fold," Nature Struct. Biol., Vol. 3, pgs. 128-132 (1996).	
	8	Bachmann et al., New England Journal of Medicine, Vol. 304, pg. 543 (1981).	
	9	Batshaw and Brusilow, "Valproate-induced hyperammonemia," Annals of Neurology, Vol. 11, No. 3, pgs. 319-21 (1982).	
	10	Bearman, S.I., "Venoocclusive disease of the liver: Development of a model for predicting fatal outcome after marrow transplantation," Journal of Clinical Oncology, Vol. 11, pgs. 1729-1736 (1993).	
	11	Beaucage et al., "Deoxynucleoside phosphoramidites - a new class of key intermediates for deoxypolynucleotide synthesis," Tetrahedron Letters, Vol. 22, pgs. 1859-1862 (1981).	
	12	Beaumier, L., "Arginine: New and exciting developments for an 'old' amino acid," Biomedical & Environmental Sciences, Vol. 9, pgs. 296-315 (1996).	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	13	Becker et al., Archives of Biochemistry & Biophysics, Vol. 223, pgs. 381-392 (1983).	
•••••••	14	Bernard et al., Intensive Care Medicine, Vol. 20, pgs. 225-32 (1994).	
	15	Boger, R. H., Curr Opin Clin Nutr and Met Care (2008) 11:55-61.	
	16	Bourrier et al., Prese Medicale, Vol. 17, pgs. 2063-2066 (1988).	
	17	Caroline et al., "Acute L-arginine supplement and cardiac surgery," Canadian J. Anesth., /D. Vol. 43, pg. A16 (1996). Dagensis, C. et al (correct author name)	B.J./
	18	Castillo et al., "Whole body arginine metabolism and nitric oxide synthesis in newborns with persistent pulmonary hypertension," Pediatr. Res., Vol. 38, pgs. 17-24 (1995).	
200000000000000000000000000000000000000	40	Castille et al., Journal of Biological Chemistry, Vol. 264, pgs. 4038-44 (1989).	000000000
**************************************	20	Castro-Gago et al., Child Neuro Systems, Vol. 6, pgs. 434-436 (1990).	
	21	Cervera et al., "Photoaffinity labeling with UMP of lysine 992 of carbamyl phosphate synthetase from Escherichia coli allows identification of the binding site for the pyrimidine inhibitor," Biochemistry, Vol. 35, pgs. 7247-7255 (1996).	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

^{*}EXAMINER: Initial if reference considered, whether of not citation is in conformance with MPEP 609. Draw line through citation in not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitu	ute for form 1449B/PTO		55 communication (10 pg to 10	Complete if Known		
Oubout	no for form 1440B/1 10			Application Number	10/785,374	
INF	ORMATION DISC	:1 05	URF	Filing Date	2/24/2004	
	ATEMENT BY AP			First Named Inventor	Summar et al.	
317	AIEWIENI DI AF	PLIC	AINI	Art Unit	1638	
	(Use as many sheets as necessary)			Examiner Name	Diana B. Johannsen	
Sheet	3	of	7	Attorney Docket Number	1242/58 CIP	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	22	Cheung et al., "Channeling of Urea Cycle Intermediates in Situ in Permeabilized Hepatocytes," J. Biol. Chem., Vol. 264, pgs. 4038-4044 (1989).	
***************************************	23	Cohen P. P., Current Topics in Cellular Regulation, Vol. 18, pgs. 1-19 (1981).	
	24	Conner et al., Proc. Natl. Acad. Sci. U.S.A. 80:278(1983).	
	25	Coude et al., J. Clin. Invest., Vol. 64, pgs. 1544-1551 (1979).	
	26	Coulter et al., Lancet, Vol. 1, No. 8181, pgs. 1310-1311 (1980).	
***************************************	27	Crea et al., Proc. Natl. Acad. Sci. USA, Vol. 75, pgs. 5765-5769 (1978).	
	28	de Groot et al., Biochemical & Biophysical Research Communications, Vol. 124, pgs. 882-888 (1984).	
	29	Eadie et al., "Valproate-associated hepatotoxicity and its biochemical mechanisms," Med. Toxicol., Vol. 3, pgs. 85-106 (1998).	
***************************************	30	Eichenlaub et al., "Mutants of the mini-F plasmid pML31 thermosensitive in replication," J. Bacteriol., Vol. 138, pgs. 559-566 (1979).	
***************************************	31	Faber-Langendoen et al., Bone Marrow Transplantation, Vol. 12, pgs. 501-507 (1993).	
	32	Fike, C. D. et al., J Appl Physiol (2000) 88:1797-1803.	
	33	Fike, C. D., et al., American Journal of Physiology (Lung, Cellular and Molecular Physiology 18) (1998) 274:L517-L526	
	34	Gribskov et al., "Sigma factors from E. coli, B. subtilis, phage SP01, and phage T4 are homologous proteins," Nucl. Acids. Res., Vol. 14, pgs. 6745-6763 (1986).	
	35	Hauser et al., "Allopurinol-induced orotidinuria," New England Journal of Medicine, Vol. 322, pgs. 1641-1645 (1990).	
	36	Hebert, P.C., "A simple multiple system organ failure scoring system predicts mortality of patients who have sepsis syndrome," Chest, Vol. 104, pgs. 230-235 (1993).	
	37	Jackson M. J., Annual Review of Genetics, Vol. 20, pgs. 431-64 (1986).	
	38	Javid-Majd et al., "Comparison of the Functional Differences for the Homologous Residues within the Carboxy Phosphate and Carbamate Domains of Carbamoyl Phosphate Synthetase," Biochemistry, Vol. 35, pgs. 14362-14369 (1996).	
**************************************	39	Jones et al., "Venoocclusive disease of the liver following bone marrow transplantation," Transplantation, Vol. 44, pgs. 778-783 (1987).	
	40	Kamoun et al., "Valproate-induced inhibition of urea synthesis," Lancet, Vol. 1, pg. 48 (1987).	

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

^{*}EXAMINER: Initial if reference considered, whether of not citation is in confidence with MPEF 609. Draw line through citation in the information and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 07/31/20. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitu	ute for form 1449B/PTO				Complete if Known
				Application Number	10/785,374
INF	ORMATION DISC	21.05	SURF	Filing Date	2/24/2004
	ATEMENT BY AP			First Named Inventor	Summar et al.
317	AILMENT DI AF			Art Unit	1638
	(Use as many sheets as ne	cessary)		Examiner Name	Diana B. Johannsen
Sheet	4	of	7	Attorney Docket Number	1242/58 CIP

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	41	Kinsella et al., "Low-dose inhalational nitric oxide in persistent pulmonary hypertension of the newborn," Lancet, Vol. 340, pgs. 819-820 (1992)	
	42	Kyte & Doolittle, "A simple method for displaying the hydropathic character of a protein," J. Mol. Biol., Vol. 157, pgs. 105-132 (1982).	
	43	Landgren et al., Science, 241:1007, (1988).	
	44	Landgren et al., Science, 242:229-237, (1988).	
	45	Lipsitz et al., "Endogenous nitric oxide and pulmonary vascular tone in the neonate," J. Pediatr. Surg., Vol. 31, pgs. 137-140 (1996)	
	46	Liu and Sommer, "Restriction endonuclease fingerprinting (REF): a sensitive method for screening mutations in long, contiguous segments of DNA," Biotechniques, Vol. 18, No. 3, pgs. 470-477 (1995).	
	47	Liu, et al., Am J Physiol Lung Cell Mol Physiol (2006) 290:L2-L10.	
	48	Maniatis et. al., in <i>Molecular Cloning: A Laboratory Manual</i> , Cold Spring Harbor, N.Y., pgs. 280-281 (1982).	
	49	Marrini et al., "Hepatic and renal contributions to valproic acid-induced hyperammonemia," Neurology, Vol. 38, pgs. 365-371(1988).	
	50	Marshall et al., "Multiple organ dysfunction score: a reliable descriptor of a complex clinical outcome," Critical Care Medicine, Vol. 23, pgs. 1638-1652 (1995).	
······································	51	Matuschak and Rinaldo, "Organ interactions in the adult respiratory distress syndrome during sepsis. Role of the liver in host defense," Chest, Vol. 94, pgs. 400-406 (1988).	
	52	Matuschak et al., American Review of Respiratory Disease, Vol. 141, pgs. 1296-1306 (1990).	
	53	Matuschak, G. M., "Lung-liver interactions in sepsis and multiple organ failure syndrome," Clinics in Chest Medicine, Vol. 17, pgs. 83-98 (1996).	
	54	McCaffrey et al., "Effect of L-Arginine Infusion on Infants with Persistent Pulmonary Hypertension of the Newborn," Biol. Neonate, Vol. 67, No. 4, pgs. 240-243 (1995).	
	55	McDonald et al., "Veno-occlusive disease of the liver and multiorgan failure after bone marrow transplantation: a cohort study of 355 patients," Annals of Internal Medicine, Vol. 118, pgs. 255-267 (1993).	
***************************************	56	Meier, U., Pharm Stat (2006) 5:253-263.	
	57	Meister, A., "Mechanism and regulation of the glutamine-dependent carbamyl phosphate synthetase of Escherichia coli.," Adv. Enzymol. Relat. Areas Mol. Biol., Vol. 62, pgs. 315-374 (1989).	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional).

Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (07-09)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitu	ite for form 1449B/PTO				Complete if Known	
2 aboutu				Application Number 10/785,374		
INF	ORMATION DISC				2/24/2004	
	ATEMENT BY AP			First Named Inventor Summar et al.		
317	ALEMENT DI AF	FLIC	JAIN I	Art Unit	1638	
	(Use as many sheets as ne	cessary)	ı	Examiner Name	Diana B. Johannsen	
Sheet	5	of	7	Attorney Docket Number	1242/58 CIP	

		NON PATENT LITERATURE DOCUMENTS	amilian täikima
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	58	Messing et al., <i>Third Cleveland Symposium on Macro Molecular and Recombinant DNA</i> , Ed. Walton, A., (Elsevier, Amsterdam) (1981).	
	59	Mitchell et al., "Syndrome of Idiopathic Hyperammonemia after High-Dose Chemotherapy: Review of Nine Cases," American Journal of Medicine, Vol. 85, No. 5, pgs. 662-667 (1988).	
	60	Moncada et al., "The L-Arginine-Nitric Oxide Pathway," New England Journal of Medicine, Vol. 329, pgs. 2002-2012 (1993).	
	61	Moorman et al., "Expression patterns of mRNAs for ammonia-metabolizing enzymes in the developing rat: the ontogenesis of hepatocyte heterogeneity," Histochemical Journal, Vol. 22, pgs. 457-468 (1990).	
	62	Mupanemunda, R. H., Early Human Development (1997) 47: 247-262.	
	63	Needleman et al., "A general method applicable to the search for similarities in the amino acid sequence of two proteins," J. Mol. Biol., Vol. 48, pgs. 443-453 (1970).	
	64	Nuzum, "Urea Cycle Enzyme Adaptation to Dietary Protein in Primates," Science, Vol. 172, pgs. 1042-1043 (1971).	
	65	Office Action corresponding to U.S. Patent Application Serial No. 12/322,434 dated April 5, 2011.	
	66	Office Action corresponding to U.S. Patent Application Serial No. 12/122,117 dated March 23, 2011.	
	67	Office Action corresponding to EP Patent Application Serial No. 10184493 dated March 30, 2011	
	68	Office Action corresponding to EP Patent Application Serial No. 05723789 dated March 31, 2011	
	69	Palmer et al., "L-Arginine is the Physiological Precursor for the Formation of Nitric Oxide in Endothelium-Dependent Relaxation," Biochem. Biophys. Res. Commun., Vol. 153, pgs. 1251-1256 (1988).	
	70	Pierson, D.L., "A rapid colorimetric assay for carbamyl phosphate synthetase I," J. Biochem. Biophys. Methods, Vol. 3, pgs. 31-37 (1980).	
	71	Price et al., "Prognostic Indicators for Blood and Marrow Transplant Patients Admitted to an Intensive Care Unit," American Journal of Respiratory & Critical Care Medicine, Vol. 158, pgs. 876-884 (1998).	
	72	Rabier et al., "Effects of organic acids on the synthesis of citrulline by intact rat liver mitochondria," Biochimie, Vol. 68, pgs. 639-647 (1986).	
	73	Rabier et al., "Propionate and succinate effects on acetyl glutamate biosynthesis by rat liver mitochondria," Biochem. & Biophys. Research Comm., Vol. 91, pgs. 456-460 (1979).	

	The state of the s		
Examiner		Date	
Signature		Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO). to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitu	ute for form 1449B/PTO				Complete if Known
				Application Number	10/785,374
INF	ORMATION DISC	CLOS	SURE	Filing Date	2/24/2004
	ATEMENT BY AP			First Named Inventor	Summar et al.
017	TILINGITI DI AI			Art Unit	1638
	(Use as many sheets as neo	essary)		Examiner Name	Diana B. Johannsen
Sheet	6	of	7	Attorney Docket Number	1242/58 CIP

		NON PATENT LITERATURE DOCUMENTS	in in a state in its and
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	74	Raiha and Suihkonen, J. Acta Paediatrica Scand., Vol. 57, pgs. 121-127 (1968).	
	75	Richardson et al., "Prevention and treatment of hepatic venocclusive disease after high-dose cytoreductive therapy," Leukemia & Lymphoma, Vol. 31, pgs. 267-277 (1998).	
	76	Rinaldo et al., "Nitric oxide inactivates xanthine dehydrogenase and xanthine oxidase in interferon-gamma-stimulated macrophages," American Journal of Respiratory Cell & Molecular Biology, Vol. 11, pgs. 625-630 (1994).	
	77	Roberts, J. D., et al., "Inhaled nitric oxide in persistent pulmonary hypertension of the newborn," Lancet, Vol. 340, pgs. 818-819 (1992)	
	78	Rodriguez-Aparicio, L. B. et al., Biochemistry, Vol. 28, pgs. 3070-3074 (1989).	
	79	Rubio, V., (Review) Biochemical Society Transactions, Vol. 21, pgs. 198-202 (1993).	
	80	Saiki et al., "A Novel Method for the Detection of Polymorphic Restriction Sites by Cleavage of Oligonucleotide Probes: Application to Sickle-Cell Anemia," Bio/Technology, Vol. 3, pgs. 1008-1012 (1985).	
	81	Schmid, R. D., Clin. Chim. Acta., Vol. 74, pgs. 39-42 (1977).	
000000000000000000000000000000000000000	82	Schwartz et al. eds. Atlas of Protein Sequence and Structure. National Biomedical	
***************************************	02	Research Foundation, pp. 357-358 (1979).	
***************************************	83	Shigesada et al., Journal of Biological Chemistry, Vol. 246, pgs. 5588-5595 (1971).	
	84	Shimoda L., et al., Physiol Res (2000) 49:549-560.	
	85	Shulman et al., "Veno-occlusive disease of the liver after marrow transplantation: histological correlates of clinical signs and symptoms," Hepatology, Vol. 19, pgs. 1171-81 (1994).	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	86	Smith et al., "Comparisons of biosequences," Adv. Appl. Math., Vol. 2, pgs. 482-489 (1981).	
	87	Stapleton et al., "Comparison of the Functional Differences for the Homologous Residues Within the Carboxy Phosphate and Carbamate Domains of Carbamoyl Phosphate Synthetase," Biochemistry, Vol. 35, pgs. 14352-14361 (1996).	
	88	Subhedar, N. V., Acta Paediatr suppl (2004) 444:29-32.	
	89	Summar ML, et al., "Physical and linkage mapping of human carbamyl phosphate synthetase I (CPS1) and reassignment from 2p to 2q35," Cytogenetics & Cell Genetics, Vol. 71, pgs. 266-267 (1995).	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitu	ite for form 1449B/PTO				Complete if Known	
				Application Number 10/785,374		
INF	ORMATION DISC	CLOS	SURF	Filing Date 2/24/2004		
	ATEMENT BY AP			First Named Inventor Summar et al.		
017	AILMLINI DI AI			Art Unit	1638	
	(Use as many sheets as neo	cessary)		Examiner Name	Diana B. Johannsen	
Sheet	7	of	7	Attorney Docket Number	1242/58 CIP	

		NON PATENT LITERATURE DOCUMENTS	onor m Hue I on a const
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	90	Summar, M. L., "Molecular genetic research into carbamoyl-phosphate synthase I: molecular defects and linkage markers," Journal of Inherited Metabolic Disease, Vol. 21, Suppl. 1, pgs. 30-39 (1998).	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	91	Toh et al., European Journal of Biochemistry, Vol. 215, pgs. 687-696 (1993).	***************************************
	92	Tse et al., "Hyperammonemia following allogeneic bone marrow transplantation," American Journal of Hematology, No. 38, pgs. 140-141 (1991).	
	93	Turley, J. E. et al., Am J Physiol Lung Cell Mol Physiol (2003) 284:L489-L500.	
	94	van den Hoff et al., "Evolutionary relationships of the carbamoylphosphate synthetase genes," Journal of Molecular Evolution, Vol. 41, pgs. 813-832 (1995).	
	95	Vosatka et al., "Arginine Deficiency Accompanies Persistent Pulmonary Hypertension of the Newborn," Biol. Neonate, Vol. 66, pgs. 65-70 (1994)	
	96	Warter et al., Revue Neurologique, Vol. 139, pgs. 753-757 (1983).	
	97	Wetmur & Davidson, J. Mol. Biol., Vol. 31, pgs. 349-370 (1968).	
***************************************	98	Wingard et al., Bone Marrow Transplantation, Vol. 4, pgs. 685-9 (1989).	
***************************************	99	Zamora et al., "Plasma L-arginine concentration, oxygenation index, and systemic blood pressure in premature infants," Crit. Care Med., Vol. 26, pgs. 1271-1276 (1998).	

	(D. D.) .	Date	/Diana R. Johannean/	Examiner
Signature Considered	 \D'R'1'\	Considered		Signature

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional).

Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.